

Humanistic Burden of Informal Caregivers of Children and Young Adults with Newly Diagnosed Type 1 Diabetes (T1D): A Systematic Literature Review (SLR)

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INTRODUCTION

- T1D is an autoimmune disease characterized by the destruction of pancreatic beta cells by the immune system, leading to reduced or absent insulin secretion.¹
- Despite the availability of injectable insulin and insulin pumps for the management of T1D, people, particularly children, require significant caregiving. Informal care is often provided by immediate family members, such as parents in the case of children with T1D.
- Studies globally have shown that caring for a child with T1D is associated with elevated levels of parental psychological distress. Previous studies have identified this complex burden and recommended targeted psychosocial interventions for the caregivers and care partners.²⁻⁴
- However, the significant and rapid developments in technology and disease management calls for an updated assessment of the humanistic and economic burden among caregivers of children, adolescents, and young adults living with T1D.

OBJECTIVE

The overarching goal of this SLR was to describe and characterize the landscape of evidence on the humanistic burden of caregivers, or parents, of children, adolescents, and young adults (ages 6 to 21) who have been newly diagnosed with T1D within approximately three months. Specifically, we aimed to describe the impact of T1D symptoms on the caregiver burden.

METHODS

- An SLR was conducted by searching MEDLINE®, Embase, and PsycInfo from database inception to December 6, 2021.
- Gray literature searches were conducted (via Embase) for abstracts published in the following conferences from 2020 to 2021:
 - American Diabetes Association (ADA)
 - European Association for the Study of Diabetes (EASD)
- After the exclusion of duplicates, two investigators reviewed all abstracts and proceedings identified through the searches and applied PICO criteria to assess eligibility:
 - Studies were included if the population included informal caregivers (i.e., persons who provide unpaid care) of children and young adults aged 6 to 21 who were diagnosed with T1D within three months.
 - Studies with any intervention or no intervention were included.
 - Included studies had any comparator or no comparator.
 - The full-text studies identified for eligibility included outcomes regarding informal caregiver perspective, symptoms, and burden.
 - Study types were randomized and non-randomized clinical trials, observational studies, and qualitative research.
- A preliminary conceptual model was developed to illustrate the humanistic burden associated with caregiving for people living with T1D.

RESULTS

- Of the five primary studies⁵⁻⁹ included (Figure 1), four were prospective cohort studies and one was a randomized controlled trial (RCT) (Table 1). No qualitative studies were identified that met the eligibility criteria.
- Three studies were conducted in the United States, one in Switzerland, and one in Australia.
- Study follow-up ranged from 14 weeks to 312 weeks (median: 48 weeks).

Patient Characteristics

- The mean age of children across studies ranged from 7.6 years to 13.2 years (median: 9.1 years).
- The proportion of female patients was reported across three studies and ranged from 39% to 53.7%.
- Most children were living with both their biological parents, 86.5%⁶ and 84.9%⁸.
- Newly diagnosed with T1D was defined as within 2 weeks after diagnosis⁵, within the first 6 weeks of diagnosis⁹, or within three months^{6,7,8}.

Caregiver Characteristics

- The mean age of caregivers was 38 years as per Sullivan-Bolyai 2015, while another study by Kovacs 1990 reported median maternal and paternal age as 37.6 years and 40 years, respectively (Table 2).
- The proportion of female caregivers ranged from 50.5% to 100%.
- Most caregivers had an intact family or were married.



POSTER HIGHLIGHT: This SLR identified that parents of children, adolescents, and young adults with newly diagnosed T1D experience caregiver burden, with mothers experiencing a greater burden than fathers.

Figure 1: PRISMA flow diagram

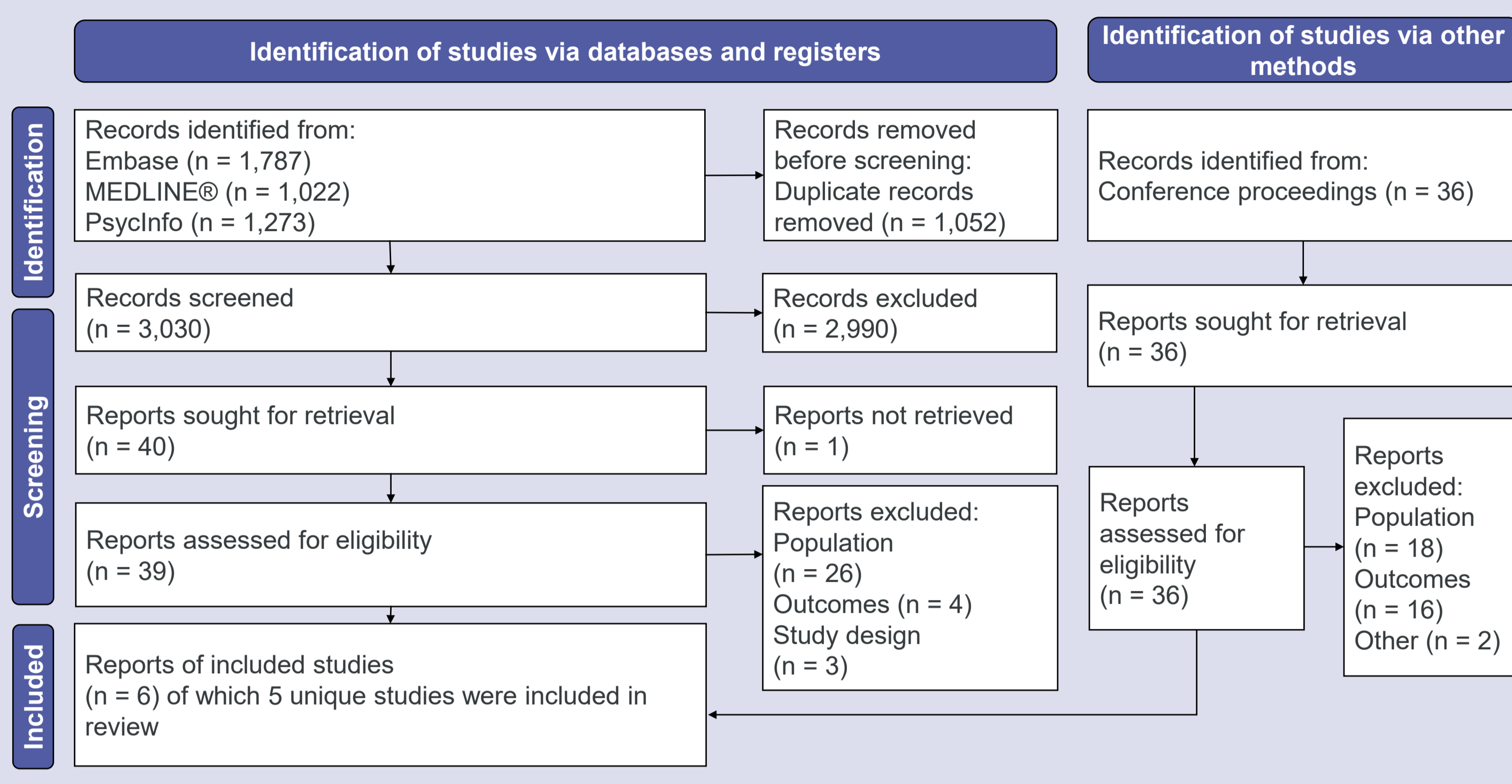


Table 1: Study characteristics

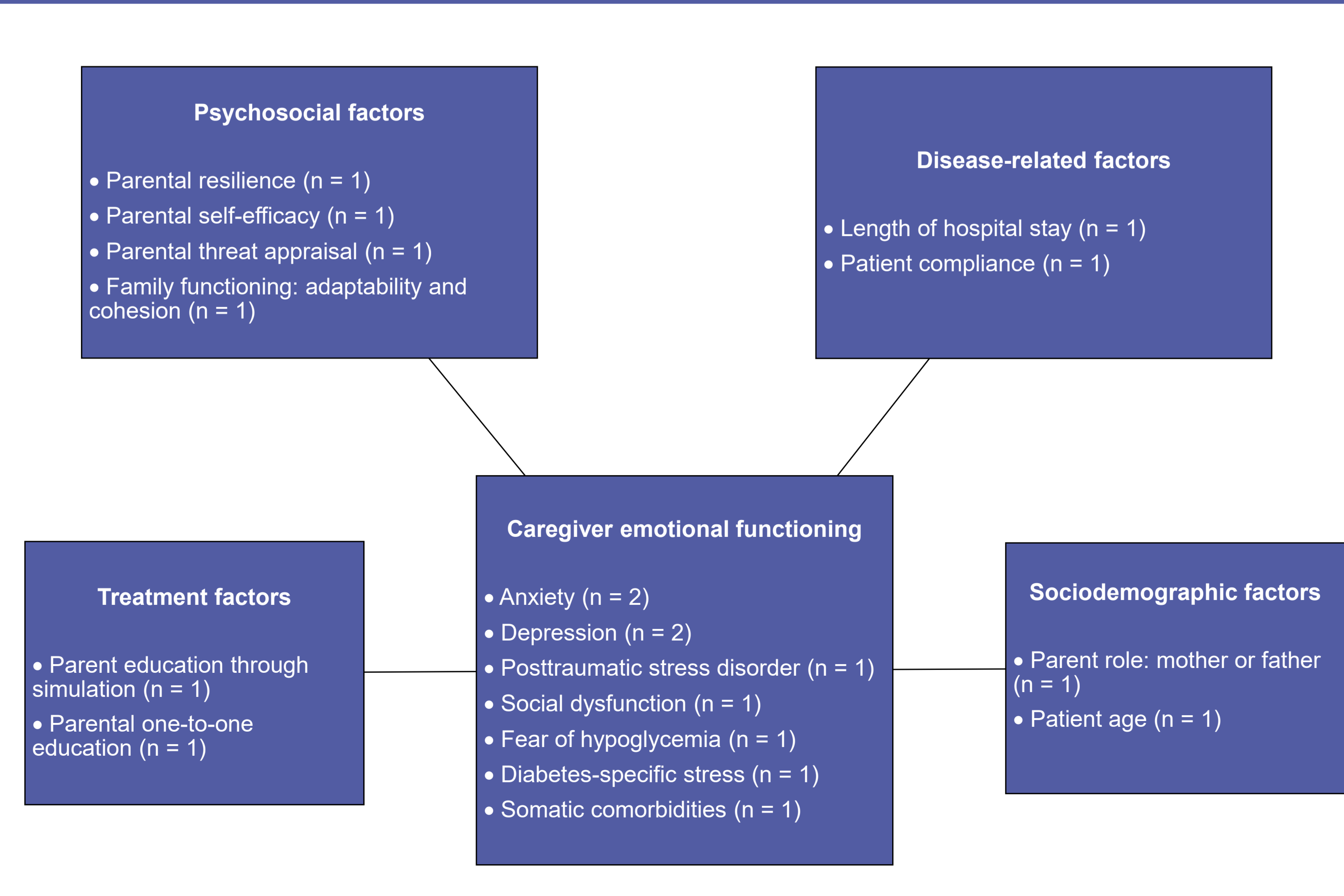
Study	Study Design	Country	Study Setting	Follow-up Length (months)	Sample Size Children	Sample Size Caregivers
Sullivan-Bolyai 2015 ⁶	Phase 3 RCT	United States	Multi center	3.2	116	191
Landolt 2005 ⁵	Prospective cohort	Switzerland	Multi center	12	52	97
Kovacs 1990 ⁷	Prospective cohort	United States	Single center	72	95	95
Northam 1996 ⁸	Prospective cohort	Australia	Single center	12	124	NR
Yi-Frazier 2018 ⁹	Prospective cohort	United States	Single center	12	59	59

Table 2: Baseline caregiver characteristics

Study	Median Age (years)	Sex, Female n (%)	Marital Status n (%)	Educational Level n (%)	Other Characteristics n (%)
Sullivan-Bolyai 2015 ^{6†}	38	59 (60.2%)	Married: 63 (64.3%); Significant other: 16 (16.3%); Divorced/separated: 12 (12.2%); Single: 7 (7.1%)	<High school or missing: 20 (20.4%); Completed high school: 28 (28.6%); Some college: 17 (17.3%); College: 20 (20.4%); Postgraduate: 13 (13.3%)	NR
Sullivan-Bolyai 2015 ^{6†}		55 (59.1%)	Married: 62 (66.7%); Significant other: 12 (12.9%); Divorced/separated: 9 (9.7%); Single: 10 (10.8%)	<High school or missing: 15 (16.1%); Completed high school: 27 (29%); Some college: 27 (29%); College: 15 (16.1%); Postgraduate: 9 (9.7%)	NR
Landolt 2005 ⁵	NR	49 (50.5%)	NR	NR	NR
Kovacs 1990 ⁷	Maternal: 37.6; Paternal: 40.7	95 (100%)	Intact family: 74 (78%)	NR	Physical health, Excellent or good: 88 (93%)
Northam 1996 ⁸	NR	NR	NR	NR	NR
Yi-Frazier 2018 ⁹	NR	NR	NR	Less than college: 27 (46%)	Income (\$100k+): 30 (51%)

† The study by Sullivan-Bolyai et al. included two intervention arms and reported characteristics stratified by intervention arm. PETS-D: Parent Education Through Simulation–Diabetes using human patient simulation; Vignette Only: One-to-one diabetes education without human patient stimulation.

Figure 2: Preliminary conceptual model of caregiver burden in newly diagnosed T1D



RESULTS (continued)

- In Landolt 2005,⁵ among parents of children aged ≤11 years, mothers had a moderate posttraumatic stress disorder symptom severity (mean score: 11.9; standard deviation [SD]: 7.4), while fathers experienced mild severity (8.4; SD: 6.2) as measured by the Posttraumatic Diagnostic Scale. This difference was statistically significant (p < 0.001).
- Northam 1996⁸ examined psychosocial and family functioning in parents of children with newly diagnosed T1D. Within 3 weeks after discharge from hospitalization of the child for diagnosis of T1D, symptoms of anxiety, social dysfunction, depression, and somatic symptoms were measured using the General Health Questionnaire (GHQ-28). Mothers experienced clinically significant symptoms (defined as score >5) of anxiety (mean score: 7.5), social dysfunction (7.5), and somatic symptoms (5.1), while fathers showed clinically significant anxiety (5.5) and social dysfunction (7.7) only.
- Results from the RCT by Sullivan-Bolyai 2015⁶ indicated that caregivers in both intervention groups experienced a greater fear of hypoglycemia at diagnosis as measured by the Hypoglycemia Fear Survey for Parents (HFS-P), which decreased over time. At diagnosis, both intervention groups showed similar levels of fear, and at 6 and 14 weeks, levels of fear in caregivers in the PETS-D intervention group were slightly higher than those in the vignette only intervention group. Additionally, among a subgroup of caregivers with children younger than 6 years old, fear of hypoglycemia was significantly higher in the PETS-D intervention group than in the vignette only intervention group over time (p = 0.03).
- Northam 1996⁸ showed that parents of children aged >11 years experienced clinically significant social dysfunction as measured by GHQ-28 with a mean score of 7.6 for mothers and 7.1 for fathers. In addition, mothers showed clinically significant symptoms of anxiety (mean: 5.4).
- Yi-Frazier 2018⁹ measured acute diabetes-specific stress by asking caregivers "What is your overall stress level about your child's diabetes right now?" on a Likert scale from 1 to 10, with a score of 1 indicating not at all stressed, a score of 5 moderately stressed, and a score of 10 extremely stressed. At time of diagnosis, the mean diabetes-specific stress score as rated by caregivers was 6.4, and this decreased to 3.5 at 3 months.
- Relevant burden and impact concepts identified from the included studies were used to develop a preliminary conceptual model of the caregiver burden in newly diagnosed T1D. Burden and impacts were categorized under overarching concepts, including treatment factors, psychosocial factors, caregiver emotional functioning, disease-related factors, and sociodemographic factors (Figure 2).

CONCLUSIONS

- Overall, this SLR highlights that parents of children, adolescents, and young adults with newly diagnosed T1D experience caregiver burden, with mothers experiencing a greater burden than fathers.
- Caregiver burden was found to be highest at diagnosis, with a slight decrease observed over time.
- Due to the paucity of evidence, further studies are warranted to better understand coping and the humanistic burden among this group of caregivers.

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DISCLOSURES

Veleka Allen, Stephanie Bascle, Aymeric Mahieu, and Andriy Cherkas report employment with Sanofi. Ren Chen Min, Ellen Kasireddy, Divya Pushkarna, and Mir-Masoud Pourrahmat report employment with Evidinno Outcomes Research Inc. Authors report no other conflicts of interest.

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